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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,318	05/31/2001	David Fikstad	WP 2001.00	1207

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 11/05/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/871,318

Applicant(s)

FIKSTAD ET AL.

Examiner

Micah-Paul Young

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-5 and 14-19 is/are allowed.
- 6) ☒ Claim(s) 1,2 and 6-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 and 9. 6) ☐ Other: .

Art Unit: 1615

DETAILED ACTION

Papers Received

Supplemental Information Disclosure Statement filed 03/12/02 and 10/07/02 and Amendment filed 10/07/02.

Allowable Subject Matter

1. Claims 3-5, and 14-19 are allowed.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1, 2, 6, and 8 – 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al (USPN 5,780,050) in view of Patchett et al (USPN 6,043,026) and Ke et al (*Endocrinology* **139** (4): 2068–2076 (1998)). The claims are drawn to a transdermal formulation comprising lasofoxifene, a permeation enhancer and a lower alkanol. The claims also comprise a means for adhering the device to the application situs.

Jain et al teaches a formulation for the transdermal delivery of a composition in combination with estrogen-like hormones. The formulation comprised a drug reservoir and a backing layer. The formulation further comprises penetration enhancers, solvents and lower alkanols comparable to that of applicant (Abstract; col. 5, lin. 23-26, col. 7, lin. 3 – 13). The

Art Unit: 1615

reference does not name the hormone compound of applicant, yet it uses sex hormones to effect a physiological change in a subject (col. 1, lin. 12 – 24). Jain also provides a means to adhere the application situs in the adhesive matrix (col. 7, lin. 50 – 59). Patchett et al discloses a topical solution comprising lasofoxifene and other constituents similar to that of applicant. Similarities in the formulation include penetration enhancers and solvents (col. 19, lin. 7 – 53). Applicant's open claim language allows for the inclusion of other active agents, as does the formulation of Jain. Ke et al teaches the osteoporosis-fighting properties of lasofoxifene. Due to their similarities in formulation one of ordinary skill in the art would be motivated to substitute the formulation of Patchett into the transdermal structure of Jain. A skilled artisan would have been motivated to make this substitution in order to impart osteoporosis-fighting properties to the transdermal device of Jain. It would have been obvious to combine the teachings in the way with an expected result of a transdermal device with osteoporosis-fighting properties.

5. Claims 7 and 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Venkateshwaran et al (USPN 5,912,009) in view of Patchett et al (USPN 6,043,026) and Ke et al (*Endocrinology* **139** (4): 2068–2076 (1998)). The claims are drawn to a transdermal formulation comprising a free form hydroalcoholic gel, and lasofoxifene. The claims also recite a means for adhering to the application situs of a subject.

Venkateshwaran et al teaches a transdermal formulation comprising a drug reservoir or a free form hydroalcoholic gel, and penetration enhancers. The reference suggests hormones as possible transdermally delivered agents using said formulation. The reference also teaches that the compound is brought in contact with the skin in order to deliver the agents (col. 5, lin. 19-20; col. 8, 52-56; col. 10, lin. 13 – 57). Again Patchett provides the lasofoxifene compositions,

Art Unit: 1615

while Ke provides the teachings to the properties the compound possesses. Again the open language of the claims allow for the inclusion of other active agents including growth hormones. Since the composition share similar constituents, namely penetration enhancers, and solvents, one of ordinary skill in the art would have been motivated to substitute the compound of Patchett into the formulation of Venkateshwaran in order to osteoporosis-fighting properties to the formulation. It would have been obvious to combine the teachings in the way with an expected result of a transdermal device with osteoporosis-fighting properties.

Response to Arguments

6. Applicant's arguments filed 10/07/02 have been fully considered but they are not persuasive. Applicant argues:

- a. Jain et al does not suggest the use of lasofoxifene, therefore the combination of Jain and Patchett would not render the invention of applicant.
- b. Venkateshwaran et al does not shore up the deficiencies in prior references.

With regard to a, Jain provides a composition where the sex hormones are delivered transdermally in a carrier composition. The carrier composition contains lower-alkanols, cell-envelope compounds, solvents, and permeation enhancers. Patchett provides a topical composition (which is transdermal by definition) comprising lasofoxifene and similar compounds as Jain. Both references can be used in hormone replacement therapy and both deliver their compositions transdermally. Due to the open language of applicant's claims, other active compositions are permissible in the formulation, such as growth hormones, and steroids.

Art Unit: 1615

Further applicant's claims are not drawn to a specific significant transdermal structure.

Recitations of 'drug reservoirs' are not patentably distinguishable from prior art reciting topical solutions. Significant structures include limitations that define layers within a transdermal structure, such as an adhesive matrix, backing layer, etc. a drug reservoir is not limited to transdermal structures and can encompass emulsions which have agents suspended in them. It is the position of the examiner that the art presented, Jain and Patchett in combination, render the claimed invention obvious.

With regard to b, Venkateshwaran is provided as a primary reference as is not used to shore up deficiencies. The reference is used to show that it is known in the art to produce transdermal formulation comprising free form hydroalcoholic gels, and penetration enhancers that deliver hormone compositions. Patchett is used to provide the specific hormone composition. It is the position of the examiner that this combination of references renders the claimed invention obvious.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1615

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005.

The examiner can normally be reached on M-F 7:30am-4: 00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MPY
November 1, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600